

Lilly Research Laboratories A Division of Eli Lilly and Company Lilly Corporate Center \*00 AUG 15 A.9:11 Indianapolis, Indiana 46285 U.S.A.

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Phone 317 276 2000

August 14, 2000

Mr. John Gomez Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane Room 1061 Rockville, Maryland 20852

Docket No. 00D-1307, CDER 67. Guidance for Industry: "Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis" published on June 14, 2000

Dear Mr. Gomez:

Per your conversation with Dr. Greg Enas, director of U.S. Regulatory Affairs, we are providing the following letter. We clarify that Lilly's response signed by Dr. Tim Franson, dated August 4, 2000, will be available to the public through the Freedom of Information and is not confidential as erroneously noted on the stationary.

Lilly appreciates the contact by the Agency to correct the note in the upper right-hand corner stating that the information is confidential. The response from Lilly was on the draft guidance document that was published in the Federal Register on June 14, 2000.

Sincerely,

ELI LILLY AND COMPANY

Gregory G. Enas, Ph.D.

Director, U.S. Regulatory Affairs

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